

PATENT
674525-2002**REMARKS**

The Office Action requires an election under 35 U.S.C. §121 from among the following groups:

- I: Claims 2, 4-9, 19, 20, 25 and 27, drawn to a method for producing a regulatory lymphocyte comprising contacting a lymphocyte with a primed APC, classified in class 435, subclass 372;
- II: Claims 10, 11, 13 and 30, drawn to a method for producing a regulatory lymphocyte comprising contacting a lymphocyte with a regulatory lymphocyte, classified in class 435, subclass 372.3; and
- III: Claims 12, 17 and 32, drawn to a method for suppressing an immune response or treating a patient suffering from a disease characterized by inappropriate lymphocyte activity comprising administering a regulatory lymphocyte to a patient or mammal, classified in class 424, subclass 93.71.

Group I is elected, with traverse, for further prosecution in this application. Applicants reserve the right to file divisional applications to non-elected subject matter.

The Office Action further required an election of species. As to a specific substance for upregulating expression of Notch or a Notch ligand, Applicants elect immunosuppressive cytokines, with traverse. To the extent that a specific cytokine must be elected, Applicants elect IL-10. As to a Notch or Notch ligand, Applicants elect Delta, with traverse.

All pending claims are generic. It is Applicants' understanding that, upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all of the limitations of an allowed generic claim, as provided by 37 C.F.R. 1.141. It is also understood that the Examiner can broaden the search to include other species, e.g., upon determining that a species is allowable, or when there is a relationship among the species and/or number of species is not too great.

As a traverse, it is noted that the MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct. (MPEP § 803) Second, searching the additional inventions must constitute an undue burden on the Examiner if restriction is not required. *Id.* The MPEP directs the Examiner to search and examine an entire application "[i]f the search and examination of an entire application can be made without serious burden, ...even though it includes claims to distinct or independent inventions." *Id.*

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It is submitted that the criteria listed in MPEP § 803 have not been met in this case, as Applicants believe that an undue burden would not be placed on the Examiner. Indeed, any search for the methods of groups I and II would certainly be co-extensive, as they are classified in the same class and similar subclasses. In addition, groups I and II are related to producing a regulatory lymphocyte, and a search involving the methods of group I would necessarily encompass a search for the methods of group II.

Enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since the requisite showing of serious burden has not been made in the Office Action and there are relationships between the claimed combinations. Indeed, the search and examination of at least groups I and II is likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of groups I and II can be made without undue burden on the Examiner. All of the preceding, therefore, mitigates against restriction.

In view of the above, reconsideration and withdrawal of the Requirement for Restriction are requested, and an early action on the merits earnestly solicited.

Respectfully submitted,

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